Product Performance Data Evaluation Review
by Kevin J. Sweeney, Senior Entomologist

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Reviewer: Linda DeLuise

EPA Reg. No. 83558-1

Product Name: No-Fly Zone

Registrant: International Textile Group

PRIA Category: R350

Dec#: 399886

DP: 357872

Active Ingredient: 0.52% w/w permethrin PC Code: 109701

Formulation: Treated cloth to be used for production of garments that are worn by humans to protect against ticks, mosquitoes, flies, midges, and ants.

Method of Support: The product was registered in 2006 as a 'me-too' product using the 'cite-all' method of support for efficacy. The 'cite-all' method supported up to 25 washings.

For this amendment the following label changes were requested:

Request: Add product performance claim of "110 home launderings (washings)".
Remove: "Wash separately"
Remove: "Wash this and other no fly-zone treated garments together."

Study submitted:
MRID47570001 Anderson, D. and B. Dalani. 2008. Durability studies for No Fly-Zone Insect Repellent Technology (Permethrin Treated Fabrics). This is a non-GLP study summarizing the results of a variety of chemical assays with the subject product.

Review:

This study has product chemistry and wash residue data; an argument with data to support the lack of cross fabric (treated to untreated) contamination; and a discussion on water quality impacts based on the "Down the Drain" model. The study lacks efficacy data. Bioassay data are required to support an increase in the number of washings from

25 to 110. Permethrin residue data alone does not suffice as the bioavailability of permethrin in the fabric as a repellent and/or insecticide must be confirmed.

Purpose

To conduct product durability testing to: provide data to support 110 washings; remove the 'wash separately' statement from the label (by examining cross-contamination to other laundered fabrics); show the consistency of permethrin application across the fabric; demonstrate two years of storage stability; and assess water quality impacts following washing the subject product using the "down the drain"model. The registrant also states on page 2 of the study that this study will provide the durability data required by the Permethrin RED as part of the product performance data call-in. However, this study and associated correspondence do not serve as an official response to the permethrin data call-in.

Materials and Methods

Product Chemistry:
The authors reviewed product 2006 chemistry on pages 2-14 without mention of study MRIDs. These data were previously reviewed by S. Malak at EPA in 2006.

Procedures for wash durability testing: The laundering procedure was based on method AATC-135-2001, which can be found in Attachment #1 on page 33. Home launderings of treated fabric samples (not whole finished garments) were performed in a Kenmore Washer rated for residential use. The samples were weighed and 'ballast' fabrics (untreated samples) were added to bring the load weight to four pounds. Liquid Tide detergent was measured (45 g) and added in every wash cycle. The samples were washed on the Permanent Press cycle. The samples were washed in hot water (145^0F) with an 85^0 F rinse. Weight and permethrin retention data results were collected at 50, 75, 95, and 110 washings. Drying of the sample fabrics was performed on the permanent press cycle dryer setting at 150^0 F with a 10 minute cool down time.

Lack of Cross-Contamination (This procedure and data should also be reviewed by the Health Effects Division) Samples of treated and untreated fabrics were laundered together. The ratio of treated to untreated fabric was 3:1. Treated and untreated polyester or nylon fabrics were washed once with the untreated fabric. The untreated fabric was assayed for permethrin.

Consistency of permethrin application and the evenness (of permethrin) across fabric. The consistency of %permethrin in lots of poly-nylon blends was determined by analytical chemistry methods. However, it was unclear how evenness across the fabric was determined in these chemical assays. The exact sampling procedure was unclear.

Storage Stability Study – up to two years (Should be reviewed by the Technical Review Branch). The registrant elected to do this study. It was not required as a condition of

registration. Treated fabric was stored at room temperature for two years. End-use articles were not tested. The registrant claimed that end-use garment processing has no effect on the efficacy of the garment and therefore, it is not necessary.

Water quality impacts of permethrin treated clothing using the "Down-the-Drain (wash-off rate)" model. (This method/model and data should be reviewed by the Environmental Fate and Effects Division) The methods used to collect the reported data were based on methodology from MRID 45751902. The methods were not described in detail. However, the experiment was intended to mimic the referenced TriTec studies done in the State of California.

Results

Test Data- Wash Durability Testing and Testing by Weight.
Data were reported in histogram and table form from washing three styles of polyester-nylon fabric 110 times. Wash results showed that the % permethrin (w/w) in the fabric was: 0.48% permethrin at 50 washes; 0.45% permethrin at 75 washes; 0.44%, permethrin at 95 washes; and 0.47% permethrin at 110 washes. The labeled permethrin level is 0.52%. Raw data including chromatograms should have been included with the results. The amount of permethrin on the fabric expressed as g/m^2 or mg/ m^2 should have been calculated for comparison to values reported in the existing product performance database and science literature.

Lack of Cross-Contamination (This procedure and data should also be reviewed by the Health Effects Division). Treated polyester or nylon fabrics were washed together with permethrin untreated fabrics in a ratio of 3:1. Permethrin cross-contamination was not detected in the washed untreated samples.

Consistency of permethrin application and evenness across fabric. The results showed that, as expected, the % permethrin in the treated fabric was within the certified limits of the Confidential Statement of Formula (CSF).

Storage Stability. Results showed that permethrin levels changed minimally following two years of storage at room temperature. Data were presented in a very brief summary.

Water quality impacts of permethrin treated clothing using the "Down-the-Drain (wash-off rate)" model. (This method/model and data should be reviewed by the Environmental Fate and Effects Division) This included an estimate of contamination wastewater effluents. The results from MRID 45751902 (cited) were presented in study attachments 2 & 3. Data collected with the subject product indicated that in the first and second washings there was no permethrin loss. This result was extrapolated to conclude that since no permethrin was washed off, there was no permethrin in the wash water effluent, hence no contamination of effluent after waste water treatment. However, permethrin is lost after the second washing in detectable quantities. The effect of permethrin loss in later washings was not addressed.

Conclusion

The submitted study shows that permethrin is retained in the treated fabric for up to 110 washings. However, the study is deficient because concurrent laboratory bioassays against ticks and mosquitoes were not conducted with swatches of fabric from the analyzed samples. These studies are required to confirm that the product is efficacious after 110 washings. Therefore, the proposed label amendment changing the number of washings from 25 to 110 is not acceptable.

Entomologist's Recommendation:

EPA requires registrants to show that permethrin residue is present in treated garments and that the permethrin in the garment is available to repel/knockdown/kill ticks and mosquitoes.

1. Conduct in-vitro bioassays with mosquitoes (three genera – *Anopheles*, *Culex*, *Aedes)* and ticks (three genera *Ixodes*, *Dermacentor* and *Amblyomma*). USDA methods (Petri dish bioassays) should be used. The level of success is $\geq$ 80%. The swatches of tested fabric should be analyzed to show permethrin residues are present. Assays should be conducted at 25, 50, 75, 95 and 110 washings. The efficacy studies and analytical chemistry data must be examined together. The presence of permethrin alone does not demonstrate that it is available to repel/knockdown/kill the target pests. The efficacy bioassays with mosquitoes and ticks are the most sensitive indicator of product success.
2. The data asked for above are not directly associated with the product data call-in for the permethrin RED.